AMENDMENTS TO THE CLAIMS

The following listing of the claims replaces all prior claims presented in the application. All cancellations and amendments of claims are made without prejudice or disclaimer of cancelled subject matter.

1-26. (Cancelled)

27. (Original) Isolated lercanidipine hydrochloride crystalline Form (II), which has an X-ray diffraction pattern, at wavelength Kα, as shown in Figure 12.

28. (Original) The lercanidipine crystalline Form of claim 27, wherein distances, (I/Io) ratios, and 2 θ angles of significant peaks in Figure 12 are:

D (Å)	Relative intensity (I/Io)	2 θ angle
9.3	35	9.5
6.0	45	14.7
5.49	65	16.1
4.65	52	19.1
4.27	74	20.8
3.81	41	23.4
3.77	100	23.6
3.58	44	24.8
3.54	29	25.2

29-36. (Cancelled)

37. (Original) A method of producing lercanidipine hydrochloride crystalline Form (II), which has an x-ray diffraction pattern, at wavelength Kα, as shown in Figure 12, the method comprising the steps of:

d") adding acetonitrile to lercanidipine hydrochloride and heating the mixture thus obtained to form a solution;

e") cooling of the solution of step d") and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is $\leq 2\%$; and

f") recovering the solid of step e") and drying said solid to produce the lercanidipine hydrochloride Form (II).

38. (Original) The method of claim 37 wherein said step d") comprises heating said mixture under reflux with stirring.

39. (Original) The method of claim 37 wherein said step e") comprises cooling the solution to room temperature.

40. (Original) The method of claim 39 wherein said step e") comprises stirring the solution at room temperature for 24 hours.

41. (Original) The method of claim 37 wherein drying step f") takes place in an oven.

42. (Original) The method of claim 37, wherein the crude Form is lercanidipine hydrochloride crude Form (A), lercanidipine hydrochloride crude Form (B) or lercanidipine crude Form (C).

43-50. (Cancelled)

51. (Original) A method of producing lercanidipine hydrochloride crystalline Form (II), which has an X-ray diffraction pattern, at wavelength K , as shown in Figure 12, which comprises:

d"') adding ethanol or isopropanol with a water content below 10% by weight to lercanidipine hydrochloride and refluxing to produce a solution;

e"') cooling the solution and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is $\leq 2\%$; and

f"') recovering the solid produced in step e"') to produce lercanidipine hydrochloride Form (II).

52. (Original) The method of claim 51 wherein ethanol is added in said step d''').

53. (Original) The method of claims 51 wherein the water content of the solvent in step d''') is between 5 and 10%.

54. (Original) The method of claim 51 wherein cooling in said step e''') is to a temperature between 20 and 40°C.

55. (Original) The method of claim 51 wherein step f''') comprises filtering said solid and drying in an oven.

56. (Original) A method of producing the lercanidipine hydrochloride crystalline Form (II), which has an x-ray diffraction pattern, at wavelength Kα, as shown in Figure 12, which comprises:

d'''') dissolving crude lercanidipine hydrochloride or lercanidipine hydrochloride crystalline Form (I) in a protic polar or an aprotic dipolar solvent containing up to 50% by weight of water to produce a solution;

e'''') stirring the solution of step d'''') until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is $\leq 2\%$; and

f'''') recovering the solid of step e'''') to produce lercanidipine Form (II).

57. (Original) The method of claim 56, further comprising irradiating with ultrasound and/or adding crystalline seeds of Form (II) to step e'''').

58. (Original) The method of claim 56, further comprising adding up to 60% water to the solution of step d'''').

59. (Original) The method of claim 56, wherein the protic polar solvent is an alcohol solvent.

60. (Original) The method of claim 56, wherein the alcohol solvent is selected from the group consisting of methanol, ethanol, n-propanol, isopropanol.

61. (Original) The method of claim 56, wherein the aprotic dipolar solvent is N-methyl-pyrrolidone.

62. (Original) The method of claim 56, wherein the temperature of said step d"") is between 20 and 70°C.

63. (Original) The method of claim 56, wherein stirring in said step e"") takes place at a temperature between 20 and 25°C.

64. (Original) The method of claim 56, wherein drying in said step f"") takes place at 70°C.

65. (Currently amended) An antihypertensive pharmaceutical composition comprising (1) ~~crystalline lercanidipine hydrochloride and optionally other forms of lercanidipine, wherein the crystalline lercanidipine hydrochloride is selected from the group consisting of lercanidipine hydrochloride crystalline Form (I),~~ a predetermined content of lercanidipine hydrochloride crystalline Form (II) or a combination of lercanidipine hydrochloride crystalline Form (I) and lercanidipine hydrochloride crystalline Form (II)~~, and combinations thereof~~ comprising a predetermined content of each crystalline form, and (2) at least one component selected from the group consisting of a pharmaceutically acceptable carrier or diluent, a flavorant, a sweetener, a preservative, a dye, a binder, a suspending agent, a dispersing agent, a colorant, a disintegrant, an excipient, a lubricant, a plasticizer, and an edible oil.

66. (Original) A unit dosage form comprising the antihypertensive pharmaceutical composition of claim 65.

67. (Original) The unit dosage form of claim 66 wherein the dosage form is a lercanidipine immediate release dosage form.

68. (Original) The unit dosage form of claim 66 wherein the dosage form is a lercanidipine controlled release dosage form.

69. (Original) The unit dosage form of claim 66 wherein the dosage form comprises a lercanidipine immediate release phase and a lercanidipine controlled release phase.

70. (Original) The unit dosage form of claim 66, wherein the composition comprises 0.1 to 400 mg lercanidipine hydrochloride.

71. (Original) The unit dosage form of claim 70, wherein the composition comprises 1 to 200 mg lercanidipine hydrochloride.

72. (Original) The unit dosage form of claim 71, wherein the composition comprises 5 to 40 mg lercanidipine hydrochloride.

73. (Currently amended) A method of treating a subject with hypertension, coronary heart disease or congestive heart failure the method comprising administering a therapeutically effective amount of ~~lercanidipine hydrochloride crystalline Form (I),~~ lercanidipine hydrochloride crystalline Form (II)~~, or combinations thereof~~ or a combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

74. (Currently amended) A method of treating or preventing atherosclerotic lesions in arteries in a subject, which comprises administering a therapeutically effective amount of ~~lercanidipine hydrochloride crystalline Form (I),~~ lercanidipine hydrochloride crystalline Form (II)~~, or combinations thereof having a predetermined content in each of said Form I and II~~ or a

combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

75. (Currently amended) A method of treating or preventing heart failure in a subject, which comprises administering a therapeutically effective amount of ~~lercanidipine hydrochloride crystalline Form (I),~~ lercanidipine hydrochloride crystalline Form (II)~~, or combinations thereof having a predetermined content in each of said Form I and II~~ or a combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

76. (Original) The method of any one of claims 73 - 75 wherein said subject in need is a mammal.

77. (Original) The method of claim 76 wherein said subject is a human.

78. (Original) An antihypertensive composition comprising predetermined amounts of lercanidipine hydrochloride crystalline Form (I) and lercanidipine hydrochloride crystalline Form (II).

79. (Original) The antihypertensive composition of claim 78 wherein the lercanidipine hydrochloride crystalline Form (I) has a melting point of about 197-201 °C and the lercanidipine hydrochloride crystalline Form (II) has a melting point of about 207-211 °C, when said melting points are determined as DSC peaks.

80. (Original) The antihypertensive composition of claim 78 or claim 79 wherein the ratio of Form (I) : Form (II) is between 1:9 to 9:1.

81. (Original) The antihypertensive composition of claim 78 wherein the ratio of Form (I) : Form (II) is selected from the group consisting of 9:1, 7:3, 1:1, 3:7 and 1:9.

82. (Currently amended) The isolated lercanidipine crystal Form of ~~any one of claims 25, 26,~~ claim 27 or 28 comprising an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.

83. (Original) The antihypertensive pharmaceutical composition of claim 65 wherein said lercanidipine hydrochloride crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.

84. (Original) The antihypertensive composition of claim 78 wherein said lercanidipine crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm.

85. (New) A lercanidipine hydrochloride of crystalline Form II exhibiting essentially the following X-ray diffraction data:

D (Å)	Relative Intensity (I/Io)
9.3	35
6.0	45
5.49	65
4.65	52
4.27	74
3.81	41
3.77	100
3.58	44
3.54	29

86. (New) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having a melting point determined by differential scan calorimetry of 207-211°C.

87. (New) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having the Infrared spectrum (IR) as a KBr powder which shows absorption bands at 3183, 2684, 1705, 1675, 1526, 1350, 1402 and 1380 cm^{-1}.

88. (New) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having a ^{13}C-NMR solid phase spectrum which exhibits peaks at δ168.1, 166.6, 151.9, 121.9, 104.0, 102.8, 79.0, 66.0, 58.0, 49.7, 48.8, 44.3, 40.5, 29.8, 27.6, 23.5, 19.6 and 18.3 ppm.

89. (New) A composition comprising lercanidipine hydrochloride wherein at least 90% of its lercanidipine hydrochloride content is Form II.

90. (New) The composition of claim 89 wherein the composition is a pharmaceutical composition.

91. (New) The composition of claim 90 comprising from about 5 to about 40 mg of lercanidipine hydrochloride Form II.

92. (New) A pharmaceutical formulation comprising lercanidipine hydrochloride Form II which has at least one of the following pharmacokinetic profile feature when administered to a human as a 10 mg tablet; an AUC_{o-t} (ng. h/ml) of about 10.36; a C_{max} (ng/ml) of about 3.22; and a t_{max} of about 2.50.